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(54) GAS DIFFUSION CONTROLLED RELEASE DEVICE

(71) COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH
ORGANIZATION

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(74) DM

(56) AU 77782/81 LAPSED A61D 7/00
AU 55556/73 470538 A61D 7/00
AU 19250/70 449029 A61D 7/00

(57) Claim

1. A controlled release device comprising a hollow tubular body adapted to contain a solid, paste or liquid material, one end of said body being at least partly open to allow egress of the material, the other end of said body being closed, a gas-tight plunger adapted for slideable movement within the body, spring driving means located between the plunger and the closed end of the body for urging the plunger and hence the material ahead of the plunger towards the open end of the body, and wherein a membrane is provided in the closed end of the body and/or in the wall of the body adjacent the closed end whereby gas from the external environment can diffuse into the body behind the plunger and thereby allow the plunger to move under the influence of the spring means.

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11639/83
APPLICATION ACCEPTED AND AMENDED
ALLOWED 18.11.86

COMMONWEALTH of AUSTRALIA

PATENTS ACT 1952

APPLICATION FOR A STANDARD PATENT

558009

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We COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANIZATION, a body corporate established under the Science & Industry Research Act 1949, carrying on scientific and industrial research, of Limestone Avenue, Campbell, Australian Capital Territory, Commonwealth of Australia

hereby apply for the grant of a Standard Patent for an invention entitled:

"GAS DIFFUSION LIMITED CONTROLLED-RELEASE DEVICES"

COMPLETE AFTER PROVISIONAL SPECIFICATION No. 1639/83

which is described in the accompanying ^{provisional} ~~complete~~ specification.

~~Details of basic application(s):~~

Number

Convention Country

Date

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PATENT OFFICE

10

TEN DOLLARS

The address for service is care of DAVIES & COLLISON, Patent Attorneys, of 1 Little Collins Street, Melbourne, in the State of Victoria, Commonwealth of Australia.

Dated this 15th day of February 19 82.

To: THE COMMISSIONER OF PATENTS

H. W. Rimington
(a member of the firm of DAVIES & COLLISON for and on behalf of the Applicant).

11639/83

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COMMONWEALTH OF AUSTRALIA

THE PATENTS ACT 1952-1973

DECLARATION IN SUPPORT OF AN APPLICATION
FOR A PATENT

In support of the Application No. 11639/83 made by Commonwealth Scientific and Industrial Research Organization (CSIRO) for a patent for an invention entitled Gas Diffusion Limited Control Release Devices.

I, DEREK BURGESS, of CSIRO, Limestone Avenue, Campbell, in the Australian Capital Territory, do solemnly and sincerely declare that I am authorised by CSIRO, the applicant for the patent, to make this declaration on its behalf.

Ralph Henry LABY of 52 Bryson Street, Canterbury and Bruno KAUTZNER of 2 McLaurin Road, Murrumbeena both in the State of Victoria are the actual inventors of the invention and the facts upon which the applicant is entitled to make the application are as follows:-

The actual inventors are an officers of CSIRO and the invention was made in the course of their official duties with CSIRO; the applicant is therefore entitled to apply by virtue of Section 54(1) of the Science and Industry Research Act 1949.

Declared at CANBERRA, this 3rd day of May 1983

D Burgess

11639/83

COMMONWEALTH OF AUSTRALIA

55300

PATENTS ACT 1952

COMPLETE SPECIFICATION

(Original)

FOR OFFICE USE

Class

Int. Class

Application Number: 11639/83
Lodged:

Complete Specification Lodged:
Accepted:
Published:

Priority:

Related Art:

This document contains the
substantive part of the
application.

and is subject to printing.

Name of Applicant: COMMONWEALTH SCIENTIFIC and INDUSTRIAL
RESEARCH ORGANIZATION

Address of Applicant: Limestone Avenue,
Campbell,
Australian Capital Territory,
Commonwealth of Australia

Actual Inventor(s): RALPH HENRY LABY
BRUNO KAUTZNER

Address for Service: DAVIES & COLLISON, Patent Attorneys,
1 Little Collins Street, Melbourne, 3000.

Complete specification for the invention entitled:

"GAS DIFFUSION-LIMITED CONTROLLED RELEASE DEVICES"

The following statement is a full description of this invention,
including the best method of performing it known to us :-

11639/83

GAS DIFFUSION-LIMITED CONTROLLED RELEASE DEVICES

This invention relates to controlled release devices, that is devices of the type which can provide controlled delivery of material in the form of solids, pastes or liquids. Such devices are used for example, in
5 pharmaceutical and veterinary applications when the materials comprise or contain therapeutic or prophylactic drugs or other biologically active substances.

A device of the type in question is described in our Australian Patent Application No. 35908/78, with
10 particular reference to its use in the intra-ruminal administration of therapeutic agents to ruminants. The present invention is concerned with modifications to that device, not only for use in ruminant husbandry and medication but also in the general field of animal and
15 human medicine. For example, the device of the present invention may be adapted for intravaginal use. It may also be employed as a controlled release device for use in the general environment or in industrial processes.

The device described in our above-mentioned
20 Application No. 35908/78 is described in more detail hereinafter but broadly it is a variable geometry device for administration of a solid therapeutic composition and comprises a hollow body having an opening, a driving means for urging a solid therapeutic composition contained therein towards said

opening, restricting means to prevent expulsion of the solid therapeutic composition therefrom by said driving means, a resilient member forming a first configuration with the body and which is capable of being resiliently deformed to provide a second configuration in which the device is capable of being administered to a ruminant per os, said resilient member being capable of reverting to the first configuration when the device reaches the rumen after administration thereof, said first configuration being such as to substantially reduce the possibility of regurgitation from said rumen. The variable geometry device may also include a means for inserting a precast plug of said therapeutic composition into the body.

15 In the preferred form of the device, the hollow body portion comprises a cylindrical tube open at one end, the other end having a base supporting a helical spring to which a plunger is attached which plunger is capable of being urged by the spring toward the opening.

20 Our earlier application also makes reference to the limitation of capsule operation by diffusion of gas through the core of matrix, past the loose-fitting plunger, into the spring chamber. The present invention now proposes limitation of the operation of a spring driven device
25 totally to gas diffusion by using a gas-tight plunger and a gas diffusion membrane in the wall of the device connecting the spring chamber with the external environment.

According to the present invention, there is provided a controlled release device comprising a hollow
30 tubular body adapted to contain a solid, paste or liquid

material, one end of said body being at least partly open to allow egress of the material, the other end of said body being closed, a gas tight plunger adapted for slidable movement within the body, spring driving means
5 located between the plunger and the closed end of the body for urging the plunger and hence the material ahead of the plunger towards the open end of the body, and wherein a membrane is provided in the closed end of the body and/or in the wall of the body adjacent the closed
10 end whereby gas from the external environment can diffuse into the body behind the plunger and thereby allow the plunger to move under the influence of the spring means.

The plunger thus divides the body cavity into two chambers which for convenience are referred to herein
15 as the "spring chamber" and the "payload chamber", i.e., that containing the material to be delivered.

The device of the present invention may also include means to vary its geometrical form, such as the resilient, deformable member of the earlier device described above.

20 Two principal modes of operation are envisaged, and have been made to operate in practice. These are (a) transfer of gas from an external gas-phase environment to the spring chamber (figuratively described as the "lung" system) and (b) transfer of gas from an
25 external solution-phase environment to the spring chamber (figuratively described as the "gill" system). The lung system is applicable to the atmospheric or the intra-vaginal environment as described later while the gill system is particularly suited to the rumen, where the
30 environmental gases are carbon dioxide and methane. Solids, pastes and liquids can all be delivered using

these devices, the requirement for solids and pastes being that their natural dissolution or extrusion rate should be a little faster than when gas diffusion limitation is operating. When the devices are used with liquids it is desirable to include a non-return valve in the opening of the payload chamber. The operation of devices described in this application requires that the net spring force at the plunger be greater than zero as there are energy losses inevitably associated with their operation.

The net spring force (F_{NS}) is given by the equation:-

$$F_{NS} = F - A (P_0 - P)$$

where F = the spring force on the plunger

A = plunger area, and

$P_0 - P$ = pressure drop across the diffusion membrane.

Energy losses include:-

- (i) friction loss at plunger-to-body contact
- (ii) friction loss at payload-to-barrel contact (if the payload is solid material)
- (iii) rheological losses in flow processes at the opening, and
- (iv) yield pressure of a non-return valve if the payload is liquid.

Energy losses diminish the pressure drop across the diffusion membrane ($P_0 - P$) which slows the diffusion rate. It is therefore advisable to reduce these losses to a minimum, and in particular to avoid non-Newtonian flow, which causes pulsating delivery. Plungers which operate by a process of alternate sticking and slipping (at a yield stress) or that show a yield stress well above operational friction can also cause pulsating delivery.

With a view to overcoming these problems, we have designated a form of plunger, for use in the device of the invention, which has low initial yield stress and frictional resistance. This plunger, which is an
5 important aspect of this invention, essentially comprises a disc of a waxy solid material having lubricating properties and compression means for providing compressive forces on the disc in an axial direction, thereby to cause the disc to expand radially. The circumference of the
10 disc is thereby forced against the inside walls of the body and a small amount of the lubricant is transferred to the walls thus lowering the yield stress and frictional resistance.

The relevant properties for the lubricant in this
15 context are that it should be a waxy solid at the temperature of use (e.g., 39°C for ruminants) and that it should have just sufficient resistance to flow under the action of the plunger spring to prevent it being forced out between plunger and barrel. Trial and error studies have
20 shown that Teric 18M2 (I.C.I. Aust. Ltd.) is a suitable lubricant for this purpose.

The compression means preferably comprises two essentially rigid discs or plates which are slightly smaller in diameter than the lubricant disc which is
25 clamped between the plates by a suitable spring mechanism, examples of which are described hereinafter. The spring mechanism in conjunction with the plates provides the necessary compressive force on the lubricant disc. Desirably the rearmost plate, i.e. that which in use
30 defines one end of the spring chamber, is provided with a circumferential flange which assists in positively locating the drive spring of the device centrally behind the plunger.

There are many variations in membrane geometry and composition that have been found satisfactory for use in the devices of this invention. For example, very slow but usable release is achieved by the use of sealed polypropylene hypodermic syringe barrels, wherein the barrel itself acts as the diffusion membrane. Specific gas diffusion rates vary over a wide range depending on the membrane materials used and the gases involved. For example, a silicone membrane material, as used in the examples given herein, is about 300 times as permeable to CO₂ as polyethylene, and carbon dioxide diffuses more rapidly through all typical non-polar membrane materials than the other gases commonly encountered in our work, namely oxygen, nitrogen, argon and methane. The size of the device is unimportant to the principle of operation. Devices sized for internal use in both sheep and cattle have been prepared from 10ml and 50ml disposable hypodermic syringe barrels (Terumo Ltd.) and work equally well.

Other subjects and features of the invention will be appreciated from the following description of some preferred embodiments. Reference will be made to the accompanying drawings in which:-

Figure 1A is a sectional view of an intraruminal device in accordance with this invention;

Figures 1B and 1C are part views of the device shown in Figure 1A showing alternative forms of the plunger;

Figure 1D is a sectional view of the experimental device described in the Examples.

Figure 2 is a graph showing the movement characteristics of the devices of Figure 1D;

Figures 3, 4 and 5 are graphs showing the performance of various devices in accordance with Figure 1D.

Figure 1A is a cross-sectional view of a variable geometry device according to the invention. The device 1 comprises a tubular body 2 having an opening 3 at one end, which opening is restricted by resilient projections 4 which protrude inwardly from said one end of the body. The other end 9 of the body is closed. The body contains a cupped gas-tight plunger 5 which is capable of sliding longitudinally thereof. The plunger is urged towards the open end (3) of the body 2 by means of a helical drive spring 6. The body has two resilient arms 7 attached thereto at said one end. The arms are attached to the body in such a manner that they normally project outwardly from said body at a suitable angle, e.g., approximately 45° , to form a first configuration. In the first configuration the device thus has the shape of an arrow-head. The arms 7 are capable of being resiliently flexed about an axis corresponding approximately with the junction of the arms with the body, to form a second configuration in which the arms are substantially parallel to the length of the body as shown by the dotted lines in Figure 1A. With the arms folded back into the second configuration the device is capable of being administered to cattle per os. As shown in Figure 1A, the body contains payload, in this instance a precast cylindrical plug 8 of a therapeutic composition. The resilient projections 4 are sufficiently flexible to allow the precast plug to be inserted into the device but have sufficient rigidity to retain the plug within the device against the pressure exerted by the spring. Alternatively, a barrier preventing ejection of the plug by action of the spring can be applied after the plug has been inserted, e.g., a strip of polypropylene welded across the opening 3 of the body. As a second alternative, the plug may be inserted from the spring end prior to insertion of the plunger and the spring.

35 The body 2, arms 7 and projections 4 may be integrally moulded from a suitable _____

plastics material such as polyethylene polypropylene or nylon. By choice of the appropriate material of construction a device may be obtained which can be retained in the rumen indefinitely or for lesser periods of time. For example, a device integrally moulded from low density, low molecular weight polyethylene will eventually fail after about 270 days in the rumen by flex cracking of the arms. On the other hand, a device integrally moulded from polypropylene is virtually indestructable.

To allow ingress of gas into the spring chamber which is defined by the plunger 5, the end 9 of the body and the walls of the body, the end 9 and/or the walls adjacent thereto are either gas-permeable or are provided with a gas-permeable membrane (not shown). In use, permeation of gas into the spring chamber allows the plunger 5 to move forward under the impetus of the drive spring 6 and hence extrude the payload 8 out of the open end of the body.

Typically the body has a length of 14cm and a diameter of 2.8cm for use in cattle, and a length of 9cm and a diameter of 1.6cm for use in sheep. The helical spring is made from spring steel wire having a circular cross-section of 0.5mm in diameter. The spring comprises 20 to 30 coils and is capable when fully compressed of exerting a pressure of approximately 600g (cattle) and 300g (sheep).

Figure 1B shows a modified form of plunger assembly in accordance with a preferred embodiment of the invention. This consists of a piston 15 formed from a suitable waxy solid material (as described elsewhere) which is supported by, and clamped between a disc 16 and a cup-shaped member 17, both of which may be made of metal or a plastics material. The diameters of disc 16 and member 17 are slightly less than the internal diameter of the body 1. The disc 16 and

member 17 are urged towards each other by a spring assembly comprising a compression spring 18, bolt 19, washer 20 and nut 21. The rear face of the member 17 abuts the end of the drive spring 6 (not shown) and transmits its pressure to the piston. The effect of the spring assembly is to compress the piston 11 axially and hence causes it to expand radially thereby ensuring good gas-tight contact between the piston and the walls of the body 1.

Figure 1C shows a further alternative form for the plunger assembly. In this case the disc 26 (corresponding to disc 16 in Figure 1B) is provided with a centrally-located blind boss 28 which passes through the piston 15. The cup-shaped member 27 (corresponding to 17) also has a centrally-located, open-ended boss 29 sized to allow free movement of the boss 28 within it. The disc 26 and member 27 are urged towards each other by a tension spring 31 attached to the bottom of boss 28 and to a bar 22 or like member spanning the free end opening of boss 29.

Obviously, other variations are possible for the plunger assembly construction.

The device shown in Figure 1D is an experimental controlled release device for use in rumen fistulated cattle. It comprises a disposable polypropylene hypodermic syringe barrel 41 which has the usual flange 42 at its open end 43 and a nozzle portion 44 at the other end which normally receives the hypodermic needle (not shown). A diaphragm 46 consisting of a gas-porous membrane material is clamped to the flange 42 by means of a pair of clamping rings 47, 48 to provide a gas-tight seal around between the flange 42 and the diaphragm 46.

The rings 47, 48 are held together by any suitable means, e.g., screws (not shown).

The plunger assembly 50 is that shown in Figure 1B.

5 Using the device described in Figure 1D various trials have been performed. Details of results are given in the following examples which further illustrate the principles and practice of the invention.

Example 1

10 Plastic components of the plunger assembly (disc 16 or 26 and member 7 or 27 shown in Figures 1B and 1C were made of polypropylene or perspex. The compression spring of the Figure 1B plunger exerted a 1500g force and the tension spring of the Figure 1C plunger a 1200g force. The piston material used was Teric 1812 (manufactured by
15 I.C.I. Aust. Ltd.).

Typical movement characteristics for these plungers are given in Figure 2. At a movement velocity of $0.0208 \text{ mm sec}^{-1}$, these plungers show yield stresses between 100 and 400g and frictional resistances between
20 20 and 200g. By comparison, rubber plungers from the disposable syringes which provide the barrels for these studies (manufactured by Terumo Ltd.) show yield stress between 500 and 1500g and frictional resistances between 300 and 500g. In addition, at the low velocities studied,
25 the rubber plungers move in stick-slip steps on many occasions because of their elastic deformation. Also, their movement is much more sensitive to distortions in the barrel.

Example 2

Studies were carried out on the in vivo release of Teric 12A23B from intraruminal devices in accordance with this invention equipped with non-return valves.

5 Two devices as depicted in Figure 1D were prepared from 50ml disposable "Terumo" syringes. They contained 45ml of "Teric" 12A23B (I.C.I. Aust. Ltd.) which is an antibloat agent, solid at room temperature and liquid at 39°C and were equipped with Figure 1B plungers and
10 drive springs of 330 20g at 75% compression. The diaphragm 46 was a 20mm diameter, 1.25mm thick silicone membrane, reinforced type 501-1 (Dow Corning Corp.). The nozzle ends of the syringes were fitted with non-return valves fashioned from No. 33 Suba seals by splitting the
15 seals with a razor blade. Rumen gases moved from ruminal solution to the spring chamber mainly through the silicone membrane. The performance of the devices are shown in Figure 3, showing plunger travel as a function of time.

Example 3

20 In vivo release of Teric 12A23B was studied as in Example 2, but the devices equipped with capillary outlets instead of non-return valves.

Four devices were constructed as described in Example 2. One device was equipped with a non-return valve, as in
25 Example 2, and three with capillary outlets:-

- (a) 10mm x 1mm diameter stainless steel
- (b) 40mm x 1.66mm diameter polyethylene capillary and
- (c) 20mm x 1.66mm diameter polyethylene capillary.

Results are given in Figure 4, expressing the amount of Teric 12A23B (ml) released with time in the rumen of fistulated cattle. The device fitted with the stainless steel capillary ran at the rate shown in Figure 4 for 5 180 days when it was removed. Capillaries are prone to blockage when used in this manner, and we have found that the outlet to the rumen should be covered with a gauze or a sintered plastic disc to prevent blockage.

Example 4

10 The operation was examined of devices in which the diffusion of atmospheric air through a membrane limits the output rate.

 Devices were prepared from 50ml "Terumo" disposable syringe barrels as described in Example 2, but 15 with reinforced silicone membranes of 32mm diameter, and thickness 0.5 or 0.2mm as specified, Figures 1B and 1C. plungers (see Example 1) and containing water instead of another biologically active fluid of some specific nature. Drive springs were of 400g strength at 75% compression. The capsules were not fitted with capillaries 20 or non-return valves. They were fitted with sealing caps which were removed at the start of the experiments. For the experiments, the capsules were placed in an air incubator at 39°C. Results are given in Figure 5.

25 This example applies to an intravaginal implant where access of atmospheric air to the external surface of the diffusion membrane is achieved by a fine plastic tube which serves a further purpose as the means of withdrawing the device when required. It also applies 30 to general environmental devices, e.g., for the dispensing of insect pheromones at rates slower than their evaporation rates.

Example 5

The effect of temperature on the release rate of gas diffusion limited spring driven devices.

5 Devices were prepared using 50 ml "Terumo" syringe
barrels equipped with sealing plungers as described herein
and containing layers of Teric 18M2 (I.C.I. Aust. Ltd.)
each of volume 1.6 ml. Drive springs were 400 g force at
75% compression. Membranes were reinforced silicone
0.18 mm thick and 28 mm exposed diameter. Devices con-
10 tained 50 ml water and were maintained in vitro at
25°C, 39°C and 45°C in duplicate. Mean release rates are
given in table below:-

| | Temperature °C | Mean Release Data ml, d | Duration of measurement, days |
|----|-------------------|----------------------------|----------------------------------|
| | | | |
| 15 | 45 | 4.67 | 1 to 6 |
| | 39 | 3.20 | 1 to 10 |
| | 25 | 1.47 | 1 to 20 |

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A controlled release device comprising a hollow tubular body adapted to contain a solid, paste or liquid material, one end of said body being at least partly open to allow egress of the material, the other end of said body being closed, a gas-tight plunger adapted for slidable movement within the body, spring driving means located between the plunger and the closed end of the body for urging the plunger and hence the material ahead of the plunger towards the open end of the body, and wherein a membrane is provided in the closed end of the body and/or in the wall of the body adjacent the closed end whereby gas from the external environment can diffuse into the body behind the plunger and thereby allow the plunger to move under the influence of the spring means.

2. A controlled release device as claimed in Claim 1, wherein the gas tight plunger comprises a disc of waxy solid material having lubricating properties, and compression means for providing compressive forces on the disc in an axial direction, thereby urging the disc to expand radially.

3. A controlled release device as claimed in Claim 2, wherein the disc of waxy material having lubricating properties is stearylamine diethoxylate.

4. A controlled release device as claimed in Claim 2, wherein the compression means comprises two essentially rigid plates which are slightly smaller in diameter than the lubricant disc which is clamped between the plates by a spring mechanism.

5. A controlled release device as claimed in Claim 1, wherein the gas tight plunger comprises an elastic or resilient moulded material containing a waxy lubricant under compression so that the waxy lubricant is forced to expand radially against the inside walls of the tubular body.

6. A controlled release device as claimed in Claim 1, wherein the gas diffusion membrane is composed of a material selected from the group consisting of polypropylene polyethylene, natural rubber, polyvinylchloride and silicone.

7. A controlled release device as claimed in Claim 1 and adapted to contain a liquid, said device including a non-return valve in the open end of the tubular body.

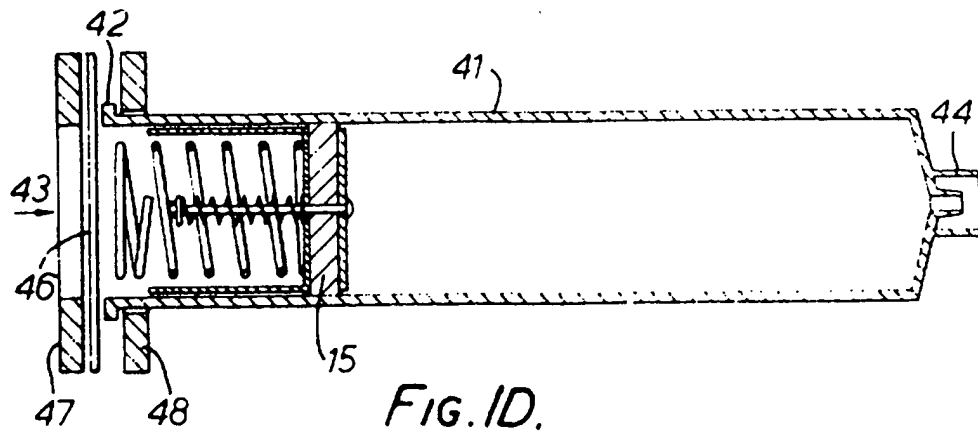
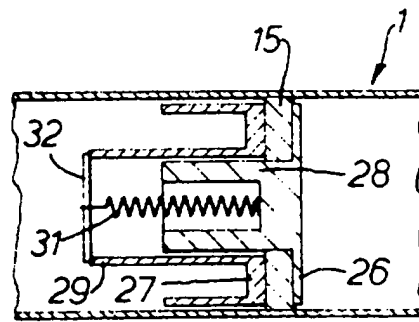
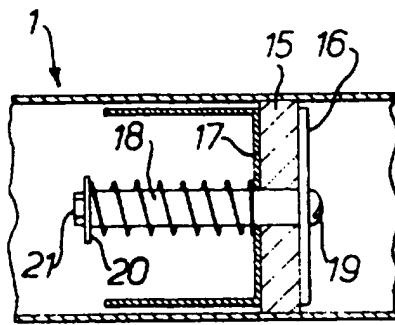
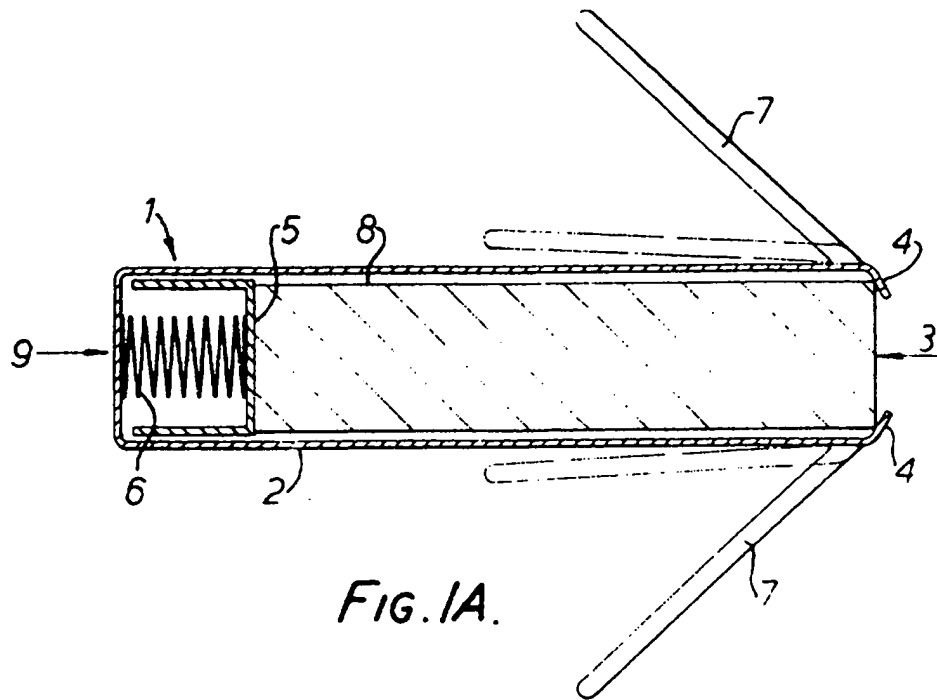
8. A controlled release device as claimed in Claim 1 and including a resilient member forming a first configuration with the tubular body and which is capable of being resiliently deformed to provide a second configuration in which the device is capable of being administered to an animal, said resilient member being capable of reverting to the first configuration when the device reaches the desired position within the animal after administration thereof, said first configuration being such as to substantially reduce the possibility of expulsion from the animal.

9. A controlled release device as claimed in Claim 1 and substantially as herein described with reference to Figures 1A - 1D of the drawing.

10. A controlled release device as claimed in Claim 1 and substantially as herein described with reference to any one of the Examples.

~~11. The steps or features disclosed herein or any
combination thereof.~~

DATED this 7th day of February, 1983
COMMONWEALTH SCIENTIFIC and INDUSTRIAL
RESEARCH ORGANIZATION
by its Patent Attorneys
DAVIES & COLLISON.



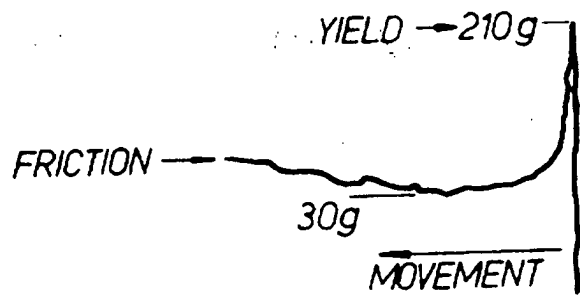


FIG. 2.

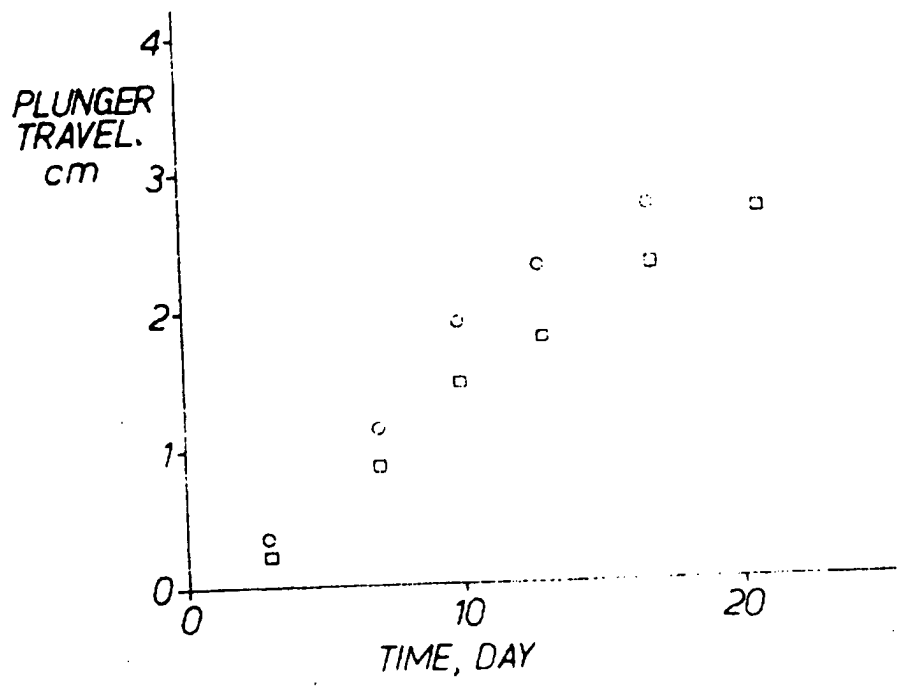


FIG. 3.

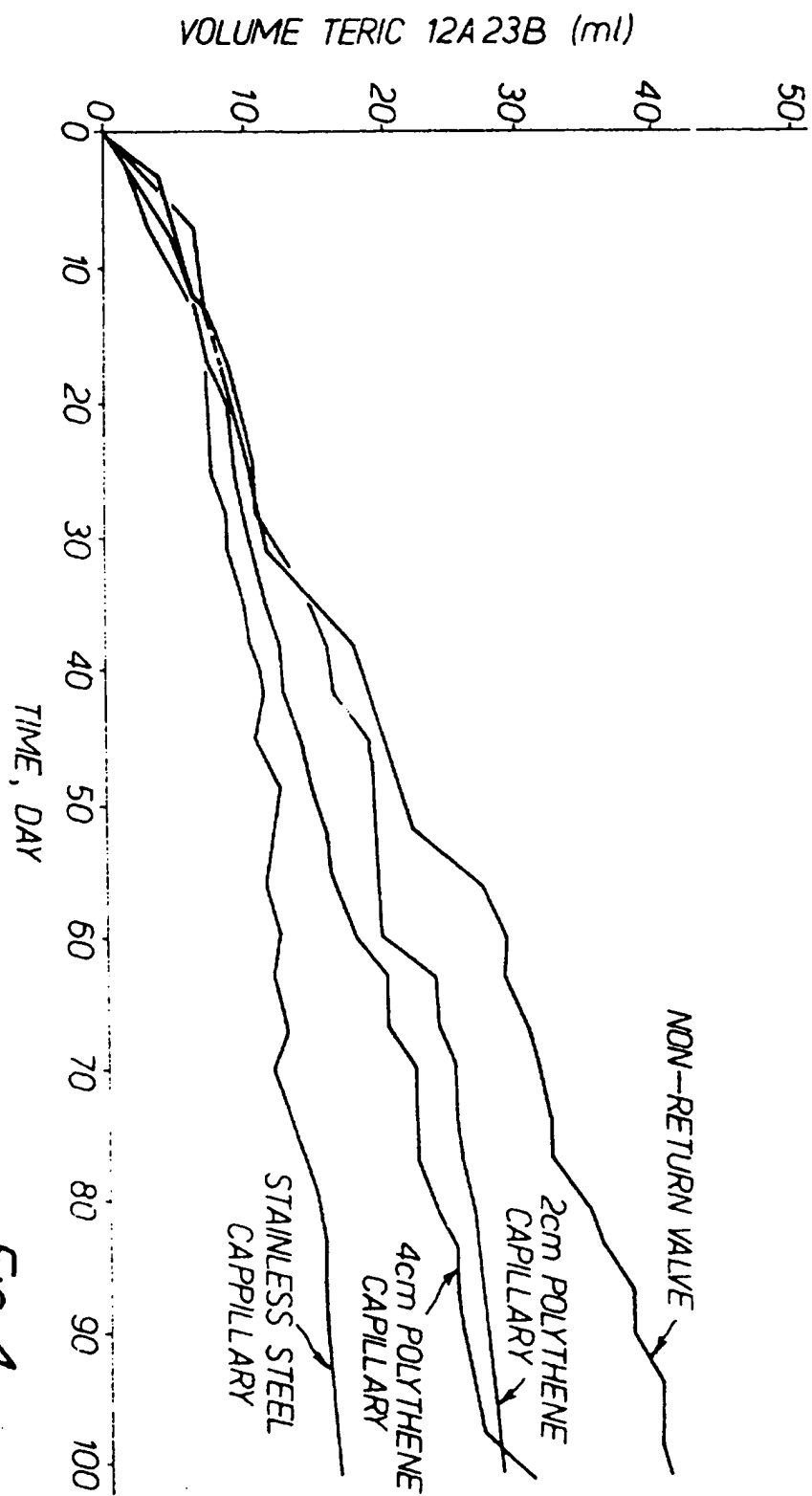


FIG. 4

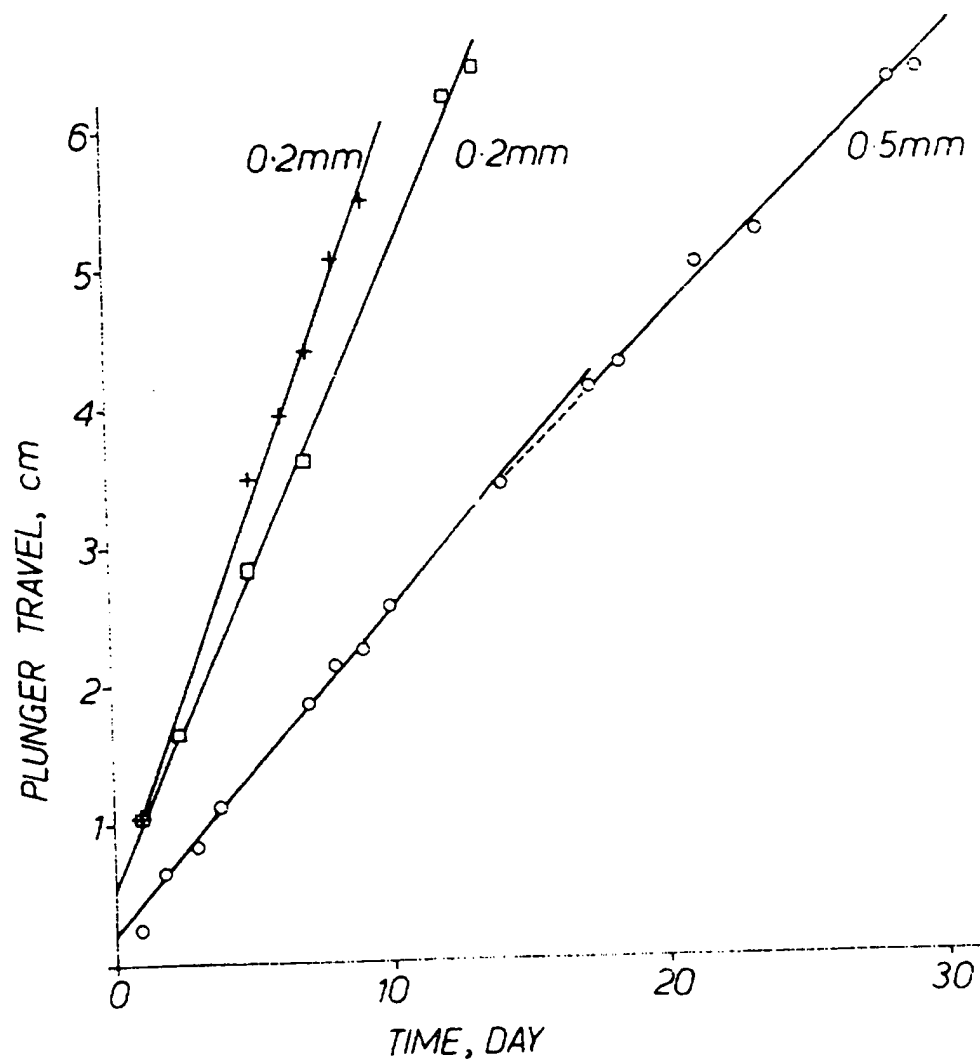


FIG. 5.

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